TSRH® Spinal System
510(k) Summary
March 2009

AUG 14 2009

I. **Company:** Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: Lila Joe
Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** TSRH® Spinal System

III. **Classification Names**

Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System, and Pedicle Screw Spinal System.

Class: II, III

Product Code(s): KWP, MNI, MNH, NKB

Regulation No.: 888.3050, 888.3060, 888.3070

IV. **Description**

The purpose of this Special 510(k) is to add the subject devices which consist of bone screws, set screws, and connectors to the TSRH® Spinal System.

The TSRH® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

The TSRH® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, staples, plates and connecting components as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other Medtronic spinal systems can be used with the TSRH® Spinal System. These components include GDLH® rods, GDLH® rod/bolt connectors, GDLH® Variable Angle T-Bolts, GDLH® set screws and locking screws, DYNALOK® PLUS™ bolts, CD HORIZON® Low Profile MULTI-SPAN®

CROSSLINK® Plates, VANTAGE™ Anterior Fixation System screws, and CD HORIZON® rods, set screws and locking screws.

The hooks are intended for posterior use only and the staples are for anterior use only. The TSRH-3D® and TSRH-3Dx™ connectors and TSRH-3D® and TSRH-3Dx™ screws are intended for posterior use only. ALL CROSSLINK® Plates are for posterior use and the CROSSLINK® Axial and Offset Plates may be used anteriorly as well.

The TSRH® Spinal System components are fabricated from medical grade stainless steel. Alternatively, they may be fabricated from medical grade titanium alloy or medical grade titanium. The subject components will be manufactured from medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or ISO 5832-2. The TSRH® Spinal System may be sold sterile or non-sterile.

V. Indications for Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients using bone graft, the TSRH® Spinal System is indicated for one or more of the following: (1) degenerative disc disease(defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3)
fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated for skeletally mature patients using bone graft: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint: (2) who are receiving fusions using autogenous bone graft only: (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis,

(6)pseudarthrosis, (7) tumor resection, and/or (8) unsuccessful previous attempts at spinal fusion.

When used as a unilateral supplemental fixation device in the antero-lateral thoracic/lumbar region, the TSRH® L-Plate and VANTAGE™ screws are intended for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthritis; and/or failed previous fusion.

For anterior use only the TSRH® Spinal System has the additional indication of: spondylolysis.

IV. Substantial Equivalence:

The subject components (bone screws, set screws and connectors) were demonstrated to be substantially equivalent to TSRH® Spinal System components manufactured by Medtronic Sofamor Danek and cleared by the FDA in K021170 (S.E. 07/16/2002), K022778 (S.E. 09/18/2002), and K052054 (S.E. 08/19/05) for the bone screws, and K072317 (S.E. 09/28/2007) for the set screws and connectors. Mechanical test results were provided in support of this submission. The labeling for this device is identical to that cleared by the agency in K052054 for the bone screws and K072317 for the set screws and connectors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofmaor Danek
% Ms. Lila Joe
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

AUG 14 2009

Re: K090740
Trade/Device Name: TRSH® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: July 15, 2009
Received: July 16, 2009

Dear Ms. Joe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090740

Device Name: TSRH® Spinal System

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When used as a unilateral supplemental fixation device in the antero-lateral thoracic/lumbar region, the TSRH® L-Plate and VANTAGE™ screws are intended for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthritis; and/or failed previous fusion.

For anterior use only the TSRH® Spinal System has the additional indication of: spondylolysis.

Prescription Use __X__ **OR** **Over-the-counter Use _____**
(Per 21 CFR 801.109)
(Optional 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

(EXT for MXM)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090740